NGR-05-020-634

BIOMEDICAL TECHNOLOGY TRANSFER

Applications of NASA Science and Technology

Submitted by
STANFORD UNIVERSITY SCHOOL OF MEDICINE
CARDIOLOGY DIVISION

Prepared for
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Technology Utilization Division
Washington, D.C. 20546

THE STANFORD UNIVERSITY BIOMEDICAL APPLICATIONS TEAM

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NASA TECHNOLOGY UTILIZATION

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PREFACE

This report summarizes the activities of the NASA Biomedical Applications Team program at Stanford University for the period from October 1, 1975 through September 30, 1976. This program is under the direction of Donald C. Harrison, M.D., Chief of the Division of Cardiology at the Stanford University School of Medicine. The Stanford Biomedical Applications Team program is supported under NASA Grant No. NGR 05-020-634 and its technical monitor is Harold Sandler, M.D., Chief of the Biomedical Research Division at the NASA-Ames Research Center.

For the convenience of the reader the names and addresses of medical device manufactures referred to in this report are included in Appendix B. This listing does not constitute an endorsement by either the National Aeronautics and Space Administration or the Stanford University School of Medicine.

ABSTRACT

This report covers the major efforts of the Stanford Biomedical Applications Team Program at the Stanford University School of Medicine for the period from October 1, 1975 to September 31, 1976. This program is supported under NASA Grant, NASA NGR-05-020-634 and its technical monitor is Harold Sandler, M.D., Chief of the Biomedical Research Division, at the nearby NASA-Ames Research Center. The director of this program is Donald C. Harrison, Chief of the Division of Cardiology of the Stanford University School of Medicine. During this reporting period, the Stanford BATeam, with the help of scientists and engineers at the Ames-Research Center, had made significant progress on a variety of aerospace technology projects.

A completed EMG Biotelemetry System has been delivered to the Children's Hospital at Stanford. This wide-band multi-channel patient monitoring instrument represents an adaptation of NASA experience in the field of biotelemetry in monitoring the physiological signals of man and animals in space related research.

During this reporting period, the Third International Symposium on Biotelemetry was held May 17-20, 1976 at Pacific Grove, California. Sponsored by the NASA-Ames Research Center, The Stanford University School of Medicine and the Jet Propulsion Laboratory, this international conference provided a forum for the dissemination of recent advances made by NASA in the field of physiological monitoring. Also completed during this reporting period has been the editing of the text Biotelemetry III.This publication of the proceedings of the Third International Symposium on Biotelemetry will be released in December,

1976 through Academic Press.

In order to illustrate the function of the Biomedical Applications Program the film, "Dividends From Space - Biomedical Applications of Aerospace Technology" has been completed. This color motion picture shows nurses, technicians, doctors, patients and aerospace engineers working together to bring the advances of the space program to the patient. This film is now available for showing at engineering and medical meetings as well as to the general public.

The results of a pilot study involving lower body negative pressure testing in cardiac patients has been completed as well as the design and construction of a new leg negative pressure unit for evaluating heart patients at Stanford University. This technology is based on NASA research, using vacuum chambers to stress the cardiovascular system during space flight.

Additional laboratory tests of an intracranial pressure transducer, (based on a pressure cell originally developed by NASA for wind tunnel tests of aircrafts) have been conducted. Extremely stable long term data using capacative pressure sensors has lead to the order of commerciajly manufactured monitoring systems based on the NASA design.

Projects involving commercialization are: Flexible medical electrodes, NASA echocardioscope, a miniature biotelemetry system, and an on-line ventricular contour detector. Each of these is in various stages of commercial development, including a presently marketed device (the flexible medical electrode) and a NASA developed system just recently disclosed to manufacturers (the on-line ventricular contour detector).

In addition to these on-going and completed projects, the Stanford BATeam

has identified three new biomedical problems to which NASA technology is applicable. These are: A communication device for the speech impaired, the NASA developed liquid-cooled garment and miniature force transducers for heart research. This report is concluded with a bibliography of publications which were the direct result of BATeam projects and is followed by a listing of medical device manufacturers who are involved in the commercialization of NASA technology transferred by the Stanford BATeam.

INTRODUCTION

THE BIOMEDICAL APPLICATIONS TEAM CONCEPT

The Technology Utilization Program

Biomedical Applications Teams represent an important element in the overall NASA Technology Utilization Program. The Technology Utilization Program, began in 1962, and was established for the following purposes:

1. To increase the return on the national investment in aeronautical and space programs by helping to bring about additional uses of the knowledge gained in these programs.

2. To shorten the time from the development of new knowledge to its effective utilization.

3. To aid the movement of new knowledge across organizational, disciplinary, and regional boundaries.

4. To help develop better methods for communicating and applying government generated knowledge to private industry.

The Biomedical Applications Teams

Biomedical Applications Teams (BATeams) were established by NASA in 1966 for the specific purpose of transferring aerospace technology to the solution of biomedical problems. Basically, the BATeam acts as an interface between medical researchers and NASA engineers. Team members meet with investigators in the medical and biological sciences to define significant technological problems. Only those problems are considered which meet the following criteria:

1. No ready solution is available through commercial medical instrument manufacturers.

2. The problem can be defined in such terms that an aerospace related technology could be applicable to a solution.

3. Solution of the problem would make a significant contribution to medical research or clinical medical practice.

There are four Biomedical Applications Teams established at the following institutions:

Stanford University School of Medicine
Cardiology Division
Biomedical Technology Transfer
701 Welch Road - Suite 3303
Palo Alto, California 94303

Research Triangle Institute
P.O. Box 12194
Research Triange Park
North Carolina 27709

Advisory Center for Medical Technology and Systems
University of Wisconsin
1500 Johnson Drive
Madison, Wisconsin 53706

Martin Marietta
Mail Code DE5
Lyndon B. Johnson Space Center
Houston, Texas 77058

Technology Transfer Process

There are many different ways in which technology developed through the space program can be applied or transferred to solving biomedical problems. The term technology itself is very broad including both hardware and software as well as the engineering expertise that has been a part of aerospace projects. No single approach to transferring technology to medicine is applicable to all medical problems. The approach must be adapted to the particular problem and the institutions that are involved. However, the general procedure followed by all the Biomedical Applications Teams is as follows:

First a BATeam member confers with the problem originator. Clarification of technological aspects of the problem leads to the formulation of a "Problem Statement". Besides defining the problem in greater detail, the Problem Statement answers the following questions:

1. What medical specialty is involved?
2. How has this problem been solved in the past?

3. What presently available commercial equipment is applicable?
4. What broad-based medical impact will solution of the problem have?
5. Could the technological solution offered by NASA be readily made commercially available.

Answering these questions frequently requires the use of both computerized searching, utilizing NASA data banks, and direct contact with scientific and engineering staff at the NASA field centers. Circulation of problem statements among NASA scientists and engineers frequently results in unexpected and novel approaches. Finding that a solution does exist within the NASA program, the process of technology transfer has just begun.

If after careful screening a problem is found to be of sufficient medical significance and to have a potential NASA technological solution, the BATeam then attempts to implement or transfer this aero-space solution to the medical field. Instrumentation originally designed for the space program can seldom be directly applied to a biomedical problem. Usually the medical problem originator needs assistance in implementing the NASA technology. A NASA instrument may require adaptive engineering or redesign of its capabilities before its feasibility in solving a medical problem can be demonstrated. This problem of adaptive engineering is a significant one and frequently requires the material as well as engineering resources of a NASA field center or medical device menufacturer. The prototype device must then be clinically tested to determine that it meets specified engineering and medical standards.

One of the more recent goals of the Biomedical Applications Team Program is to increase the availability of the NASA solutions through commercialization. After a biomedical problem has been screened and a unique NASA technological solution has been found, the use of this technology by other medical investigators and institutions must be considered. If the original problem has been carefully selected, there will be medical device manufacturers interested in the NASA solution. There are many criteria which enter into the decision as to whether or not medical device manufacturers will accept the new idea. Certainly profitability and the results of market studies are important considerations. If a company is interested in the innovation, NASA can then grant the company a license to manufacture and sell the device.

Commercialization, though an important objective in technology transfer, is only one facet of the BATeam program. If NASA engineering expertise can help an investigator make a significant contribution to medical research, an important transfer will have occurred even though it has not resulted in a marketable product.

The Stanford Biomedical Applications Team

The Stanford Biomedical Applications School is a nationally recognized authority in the medical speciality of Cardiology. The Stanford University BATeam functions within the Division of Cardiology and has emphasized solving urgent problems related to the heart. Previous applications of aerospace technology to this medical speciality have included projects in electrocardiography, cardiac catherization, biomedical electrodes, and ultrasound imaging of the heart. Although emphasizing Cardiology, the Stanford BATeam has found

new applications for space technology in such diverse areas as Cerebral Palsy, Neurosurgery, Orthopedics and Internal Medicine.

The Stanford BATeam is a multi-disciplinary group of scientists, doctors, and engineers. The principal members of this team are:

Donald C. Harrison, M.D.
Chief of Cardiology and Biomedical
Applications Team Director

Gene Schmidt, M.D.
Assistant Director

Harry Miller
Deputy Director

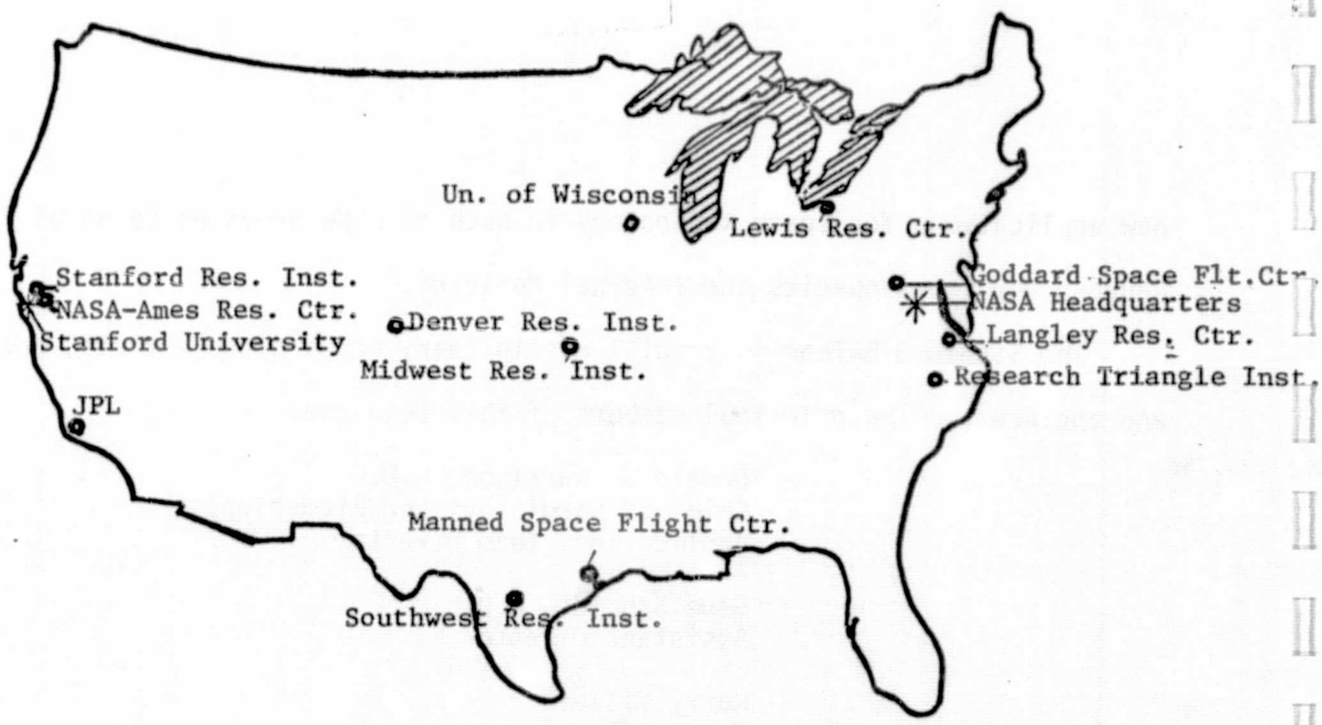
Edwin Carlson, M.D.
Cardiovascular Research Associate

Richard Popp, M.D.
Assistant Professor of Cardiology

Earceal Kidd
Program Secretary and Special
Projects Coordinator

Robert J. Debs
Manley Hood
Paul Purser
(Part-time engineering consultants)

These team members at Stanford University work in close cooperation with personnel at the nearby NASA-Ames Research Center and are expanding their interactions with other NASA Field Centers (see map).



Location of NASA Field Centers and Application Teams

Personnel at the NASA-Ames Research Center who have been involved in BATeam projects during this reporting period are:

Harold Sandler, M.D. Chief,
Biomedical Research Division

Walter Goldenrath, Ames-Wesrac,
Technical Coordinator

Robert Zimmerman, Bioengineering
Consultant

Charles Kubokawa, Technology
Utilization Officer

Robert Lee, Electronic
Instrument Development Branch

Salvadore Rositano, Electronic
Systems Engineering Branch

Richard Westbrook, Electronic
Systems Engineering Branch

Ernest McCutcheon, M.D.
Biomedical Research Division

Thomas Fryer, Assistant Chief
Electronic Instrument Development Branch

The spirit of cooperation and free exchange of ideas between the Stanford BATeam and the NASA Field Centers provides the unique breadth and depth of experience needed for identifying and implementing solutions to biomedical problems.

TECHNOLOGY TRANSFER

PROJECTS

EMG TELEMETRY IN CEREBRAL PALSY

OBJECTIVES

To utilize NASA engineering expertise in the field of miniature biotelemetry to provide a better method for monitoring the gait of children with cerebral palsy.

BACKGROUND

Children with cerebral palsy have neurological defects which severely retard their walking ability. They are frequently handicapped by spastic muscles which are in a state of constant contraction making ambulation awkward and difficult. Determining precisely which muscle groups are contributing to the child's walking difficulty is a complex problem requiring the combined talents of orthopedists and physical therapists. Direct diagnosis of the child's handicap is extremely important because there are orthopedic operations (involving tendon and muscle lengthening) which can be used to improve the child's gait.

As an aid to more accurate diagnosis, physical therapists have employed the electromyogram (EMG) to determine whether muscle groups are spastic or normal. This approach has required the use of cables extending from the child to a recording instrument. The cables necessarily encumbered the child and caused him to modify his walking pattern thereby creating inaccuracies in the record.

Two years ago NASA engineers provided assistance in implementing a waist-belt transmitter system to telemeter the EMG signal and allow the child greater freedom of motion. As he walked in his normal way, the EMG signal of individual

muscle groups within the legs were continuously transmitted, received and recorded. This approach, using biotelemetry, proved to be extremely useful in making over one hundred and fifty evaluations in the gait analysis laboratory at Stanford Children's Hospital. Analysis of these data was useful in three major areas: 1) Evaluating gait changes before and after tendon and muscle lengthening (Ref. 1) 2) Evaluation of the effect of a new muscle relaxing drug in reducing spasticity (Ref. 2) 3) Analysis of the effects of different types of braces. Although this approach was promising, it had certain major limitations (Ref. 3).

As shown in Figure 1, the original telemetry approach allowed for recording of data from only one leg at a time. Second, adjusting and securing the wires which ran from the waist-belt transmitter to the sensing electrode over the muscle groups proved to be very time consuming. Third, in smaller children and in those whose gaits were very unstable, even the three and a half pound weight of this transmitter was cumbersome and had a detectable effect on the child's normal walking pattern. Fourth, if the child fell and the waist transmitter or one of the wire connectors became damaged, the entire system was unuseable until repairs could be made. This was particularly unfortunate because the children examined and treated at Stanford Children's Hospital frequently would have to travel long distances to come back for reevaluation.

Fig. 1

Child with cerebral palsy wearing prototype waist-belt transmitter.

APPROACH

To resolve these difficulties NASA-Ames Research Center engineers have developed a broad band, crystal-controlled, miniaturized transmitter (Ref. 4). It is housed in a one inch diameter by 3/4 inch thick package which is decorated to make it more acceptable to the young child (Fig. 2).

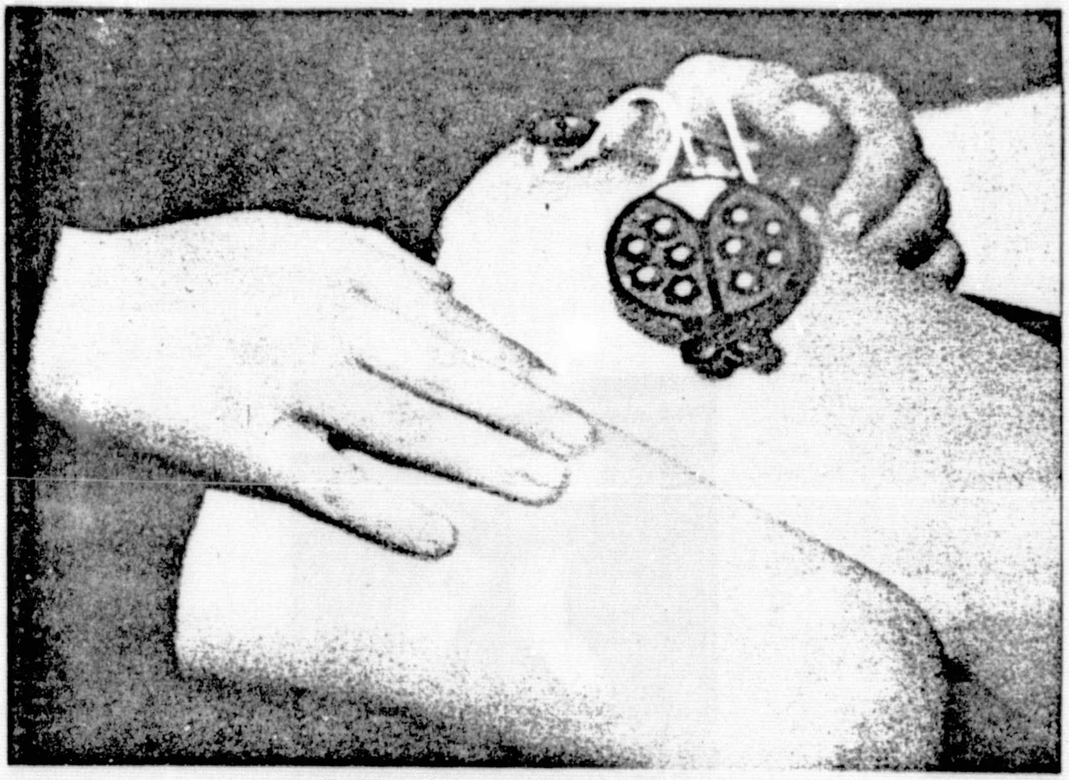


Fig. 2

Close-up of miniature EMG transmitter.

Adhesive discs are used to fasten the miniature transmitters to the leg of the child. Electrodes attached directly to the miniature transmitter pick up the electrical activity of the underlying muscle groups. The EMG signal is transmitted using a technique known as differential pulse-width modulation (DPWM). Each transmitter or "lady bug" contains two silver oxide batteries and employs a crystal in the emitter which is matched with a second crystal in the receiver (not shown). Use of matched crystals eliminates tuning difficulties and makes this system easy to use by non-engineering medical personnel. An additional transmitter is employed to transmit foot contact information so that the weight bearing and swing phases of gait can be correlated with muscle activity. As shown in fig. 3 below, the new approach eliminates both the cumbersome waist-belt package and the tangle of cables which are required in the earlier approach (Fig. 1).

Fig. 3

Cerebral palsy patient instrumented
with NASA-designed EMG transmitters.

PROGRESS

At the time of this report the new miniaturized biotelemetry system has been delivered to the Stanford Children's Hospital. Fabrication of the lady bug transmitters based on the NASA-Ames design was completed by the L&M Electronics Company, Daly City, California. In addition they designed a new wide band receiver. This completed system has been checked out and antennas have been installed in the gait analysis laboratory at Children's Hospital to eliminate any problem with signal drop-out during monitoring. Also during this reporting period, presentations and publications describing this gait analysis biotelemetry system have been completed (Ref. 3, 4).

PLANS

Although the original goal of providing a miniature biotelemetry system for analyzing the gait of small children with cerebral palsy has been achieved, some small additional electronic components are needed before this system can be used routinely in the day-to-day clinical evaluation of patients. The Stanford Biomedical Applications Team is providing some additional support in the form of an analogue to digital converter for the foot switch information and a signal calibrator to allow use of an existing strip chart recorder. These additional tasks are minor and should be completed within one month.

Once fully operational, this system will be used in the daily evaluation of children with gait abnormalities. Clinicians at Stanford Children's Hospital will be evaluating large numbers of patients referred from the north western region of the United States. This equipment will be used in direct patient care activities as well as in research programs. The Stanford BATeam has already received requests from other institutions treating handicapped children for the loan or purchase of a similiar system. We anticipate that additional requests will be received and that these orders will be filled by the L&M Electronics Company. Once commercially available to other institutions the process of transferring the NASA technology which made this project possible will be completed.

PERSONNEL:

Gene Schmidt, M.D.	BATeam Coordinator
Thomas Fryer) Salvador Rositano) Richard Westbrook)	NASA-Ames Research Center Engineers

Problem Originators:

Fran Ford, Research Physical Therapist

Eugene E. Bleck, M.D., Chief of Orthopedics and Rehabilitation, Children's Hospital at Stanford.

THIRD INTERNATIONAL SYMPOSIUM ON BIOTELEMETRY

There are many ways in which aerospace technology can be transferred to the solution of problems in biology and medicine. Sometimes this transfer process involves the fabrication of a medical instrument based upon a design developed within the space program. More frequently, however, the technology is in the form of software, i.e., new knowledge and information resulting from basic and applied research conducted at the NASA field centers. In order to make industry and university groups more aware of NASA technological advances, the Stanford University Biomedical Applications Team has periodically conducted major (frequently international) conferences on a variety of specific technological subjects. Previous conferences have included:

1. Biomedical Electrode Technology - Theory and Practice; Stanford University; September, 1973.
2. Cardiovascular Imaging and Image Processing: Ultrasound, Angiography and Isotopes; Stanford University, July, 1975.

NASA is one of the largest developers and users of biotelemetry in the world because of the need for remote monitoring of physiological signals in man and animals during space flight. Consequently, NASA has taken the lead in sponsoring the Third International Symposium on Biotelemetry. As in previous conferences, the Stanford BATeam provided origanizational, secretarial, and technical support.

More than two hundred scientists, engineers and physicians attended the 3rd International Conference on Biotelemetry held May 17-20 in Pacific Grove, California. This conference was sponsored by the Technology Utilization office at NASA-Ames Research Center, the Stanford University Division of Cardiology, and the International Society on Biotelemetry.

There were 82 speakers presenting papers in the following areas:

1. Human Research Applications
2. Implantable Telemetry Systems
3. Patient Monitoring and Clinical Telemetry
4. Neurological Applications
5. Measurements from Unrestrained Animals
6. Transducers for Biotelemetry
7. Biomedical Telemetric Equipment

Dr. Harold Sandler, Chief of the Biomedical Research Division at Ames Research Center, gave the keynote address entitled "Biotelemetry: Its First 50 Years". Dr. Normal H. Holter, President of Holter Research Foundation, Inc., and one of the pioneers of Biotelemetry spoke at a special evening session on "The Genesis of Biotelemetry".

Registrants and speakers included scientists, physicians, and engineers from the following countries: Sweden, Italy, Denmark, New Zealand, West Germany, United Kingdom, France, East Germany, Canada, The Netherlands, USSR, Japan, Switzerland, and the United States. Many of these speakers and attendees are well known international leaders in their respective fields.

Following the conference, 40 of the foreign guests returned to Palo Alto for tours of the Stanford University Cardiology Division, the Integrated Circuits Laboratory, Fairchild Corporation, and the NASA-Ames Research Center.

The proceedings of the conference will be edited and published by Academic Press in December, 1976.

CLINICAL EVALUATION OF LOWER BODY NEGATIVE PRESSURE (LBNP)

OBJECTIVE

To evaluate lower body negative pressure (LBNP) as a stress test for measuring the left ventricular function of patients with cardiac disease.

BACKGROUND

Heart disease is responsible for the deaths of more than 750,000 people each year, and is the leading cause of death in the United States. Cardiologists have developed many tests to evaluate coronary artery disease. One of the commonly used cardiac stress tests is the treadmill ECG in which a patient walks on a treadmill while his electrocardiogram is recorded and observed for signs of decreased coronary blood flow. Although this test provides important information on the state of coronary circulation during physical exercise it does not give complete information on the heart's ability to function as a pump.

At present, cardiologists evaluate the function of the left ventricle (the major pumping chamber of the heart) by examining cine-angiograms (X-ray motion pictures of the heart) taken during cardiac catherization. Cardiac catherization requires the passage of a flexible tube or catheter through a major blood vessel until it reaches the heart. Radio opague dye is injected into the heart and the ensuing ejection of the dye from the heart is recorded on X-ray film. An estimation of the pumping capacity and contractility of the heart is then made from the X-ray motion picture study.

This procedure is uncomfortable for the patient, time-consuming, expensive, and involves certain risks. An alternative, non-invasive approach to measuring

left ventricular function would provide a very useful test for evaluating cardiac patients (Ref. 5).

Lower body negative pressure testing requires placing the lower half of the body in a vacuum chamber (see fig. 1 below).

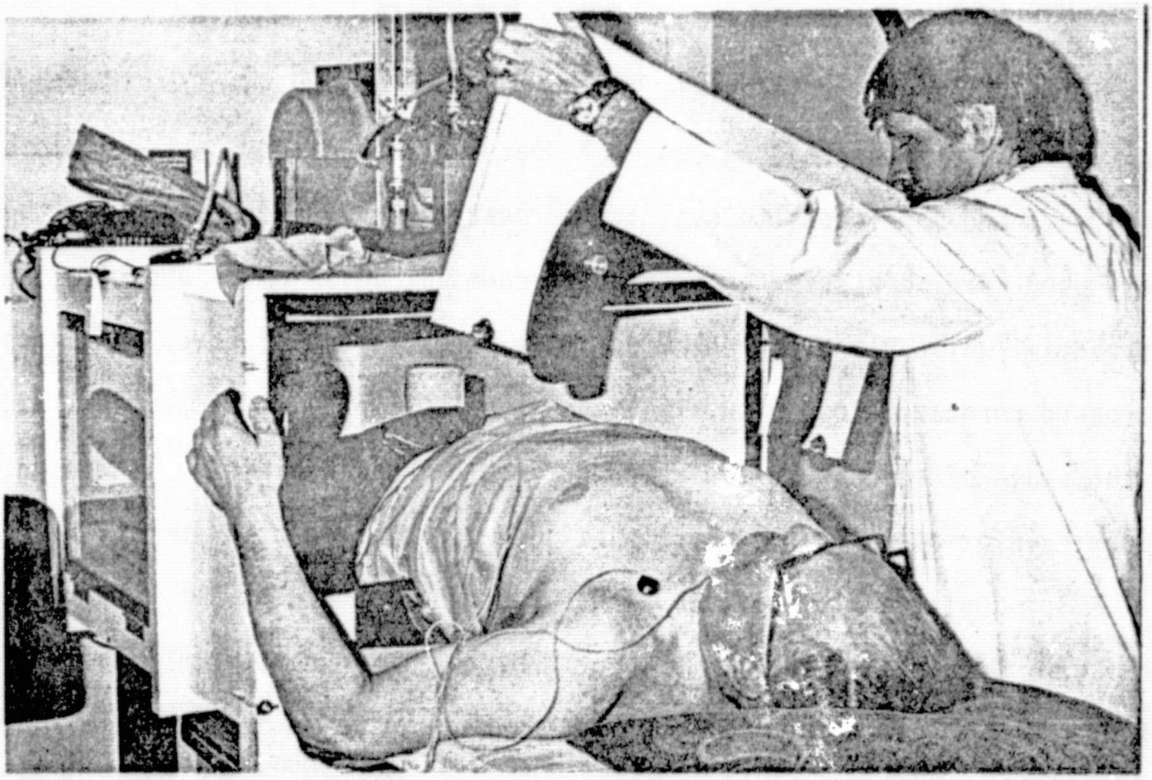


Fig. 1

Patient entering LBNP chamber. Adjustable waist-seal about to be secured.

With waist-seal in place, the chamber is then evacuated in stages. As the pressure within the LBNP unit is lowered some of the normally circulating blood is pulled down into the legs and pelvis. The amount of this pooling depends on the pressure level or suction.

Pooling of blood in the lower body causes less blood to be returned to the heart. In response to receiving less venous blood, the heart beats faster and contracts more vigorously, in an attempt to maintain previous cardiac output and blood pressure. In essence, the LBNP test provides a means for observing the cardiac response to decrease in venous return.

During an LBNP test the heart rate, electrocardiogram, and cardiac dimensions (determined using echocardiography) can be monitored non-invasively. This test, therefore, holds promise for providing a totally non-invasive method of determing left ventricular function (Ref. 6) The non-invasive measurement of blood pressure and heart volume would allow the cardiologist to determine ventricular function curves periodically to help document the improvement or worsening of a patient's condition.

NASA TECHNOLOGY

LBNP was used extensively in the space program to evaluate the cardiovascular system of astronauts. As long duration space flights became more common, the time dependent deconditioning effects of weightlessness became increasingly apparent. Flights as brief as three days caused some astronauts to faint on return to earth and standing up against the full force of gravity. In order to study the cardiovascular changes occurring during zero gravity, LBNP chambers were used in the pre and post-flight evaluation of Applo astronauts and for in-flight evaluations aboard Skylab (Fig. 2). Richard Popp, M.D., Stanford Cardiologist, participated in LBNP testing during long term bedrest studies at the NASA-Ames Research Center. This experience with normal young volunteers has made it now feasible to extend this technology to evaluate older normal subjects and cardiac patients.

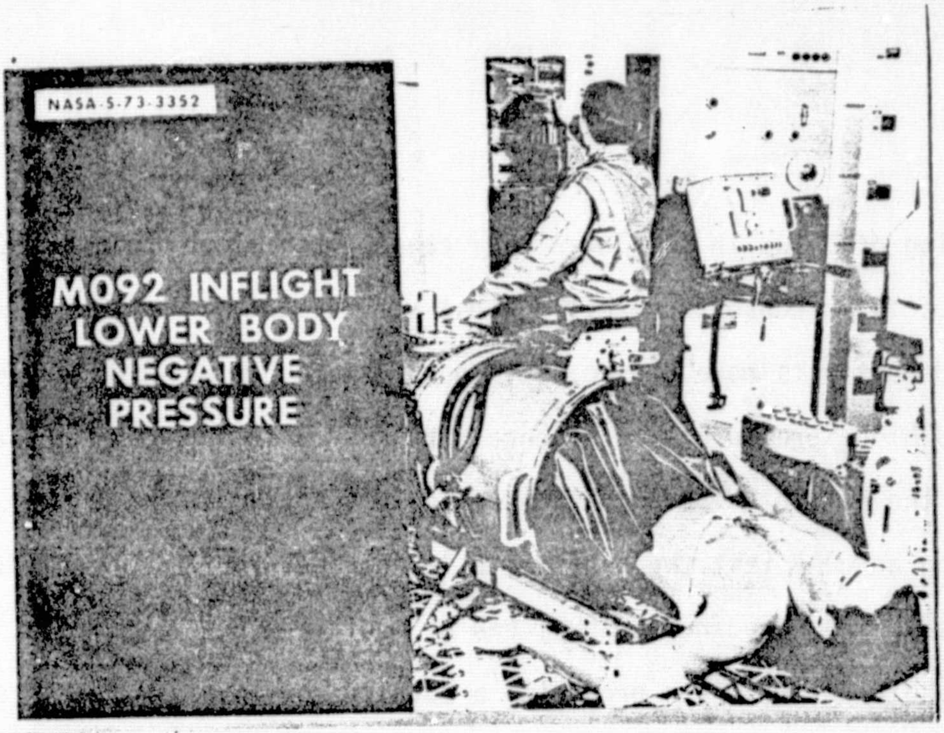


Fig. 2

SKYLAB LBNP DEVICE

PROGRESS

During this reporting period the following tasks have been completed:

1. Data from LBNP tests on older normal subjects and patients with documented coronary disease were evaluated. A total of 34 LBNP tests on 17 different individuals were involved.

2. A Cardiology research conference was held at Stanford University to review these studies and plan future patient protocols involving LBNP (a summary of this meeting was presented in April/June 1976 Quarterly Report).

3. A leg negative pressure unit (LNP) was borrowed from Dr. Roger Wolthius and Robert Johnson at the Johnson Space Center in Houston, Texas (See Fig. 3). This unit was evaluated using both echocardiography and impedance plethysmography and showed that LNP was sufficient to cause significant changes in cardiac volume.

4. Design and construction of a plexiglass leg negative pressure unit has been completed and is being tested prior to use in the cardiac catherization laboratory.

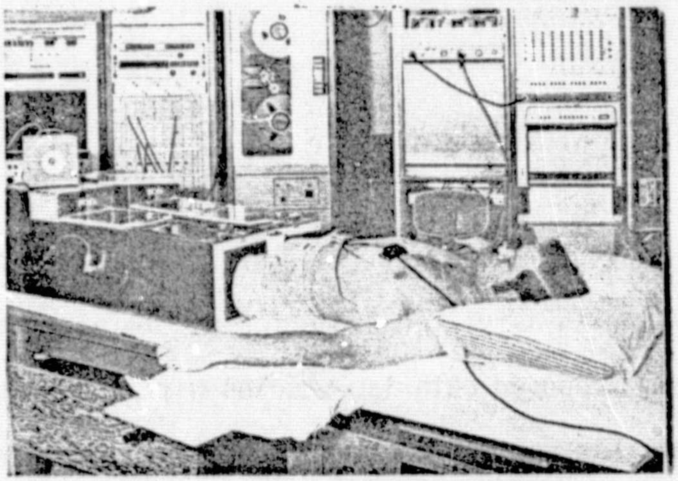


Fig. 3

Leg Negative Pressure Unit
borrowed from the Johnson
Space Center.

PLANS

The recently completed plexiglass leg negative pressure unit based on the unit loaned to us by the Johnson Space Center is being equipped for validation studies in the cardiac catherization laboratory at Stanford. Before actual patient trials are begun, this unit will be checked out in trial runs involving normal volunteers at the Cardiac Rehabilitation Laboratory.

The cath lab protocol will initially involve approximately 20 patients with coronary artery disease. After initial hemodynamic studies, these patients will be subjected to increasing stages of leg negative pressure. Levels of suction sufficient to cause changes in the left ventricular end diastolic volume will be applied. Measurement of cardiac output and cardiac pressures will be accomplished and the left ventriculogram will be recorded for comparison with volumes measured echocardiographically. Definition of the strengths and limitations of this technique in the controlled environment of the catherization laboratory will allow use of this procedure in patients undergoing studies involving the administration of cardiac drugs. Since invasive techniques have severe limitations for developing

ventricular function curves in man, it is significant that these clinical trials will offer a totally non-invasive technique for determining cardiac pump dynamics.

Besides the above proposed cath lab studies with a leg negative pressure unit, it appears that this unit will be applicable to other areas of medical investigation. Nephrologists at Stanford Medical School are interested in the renal (kidney) regulation of blood pressure and another group of investigators is studying the responses of the carotid and aortic bodies to hypertension. The LNP unit could provide a non-invasive orthostatic stress for investigating the physiological mechanisms involved in these studies.

PERSONNEL

Principal Investigators:	Richard Popp, M.D., Assistant Professor of Cardiology
	Edwin Alderman, M.D., Assistant Professor or Cardiology
BATeam Coordinator	Gene Schmidt, M.D.
Cardiology Fellow	Randolph Martin, M.D.
Engineering Technician	Cecil Profitt

INTRACRANIAL PRESSURE MONITORING

OBJECTIVES:

1. To develop a reliable system for the continuous, long-term monitoring of intracranial pressure.
2. To involve commercial manufacturing companies in this development so that the final model of this device can be manufactured and marketed for use in any hospital.

BACKGROUND:

The human brain is surrounded by a constantly circulating clear liquid called cerebro spinal fluid or CSF. If the brain suffers a severe insult (either from a blow to the head, infection, or tumor), the fluid pressure ("intracranial pressure", or "ICP") increases. The ICP may also rise during recovery from brain surgery and in children with hydrocephalus. Over 100,000 patients in the U.S. each year suffer from diseases or trauma which cause a dangerous increase in intracranial pressure. If the ICP increases excessively, the brain suffers irreversible damage. Medical and surgical techniques capable of controlling ICP are available; however, techniques for measuring this vital parameter are still not perfected. A system which could continuously and accurately measure ICP over a long period of time -- with minimal patient risk -- would have great clinical impact and would improve patient care considerably.

Under a NASA Biological Applications Team grant, the Stanford University School of Medicine and the NASA-Ames Research Center are working cooperatively to produce such a system. They have started with an Ames-developed pressure transducer carrying its own on-board electronics and antenna for telemetering the measured pressure.

RELEVANT NASA TECHNOLOGY

Earlier this year, bench tests and pressure stability trials on several types of pressure transducers had established that the type having the lowest drift and hysteresis in a capacitative transducer which had been developed at the Ames Research Center for measuring air pressure changes during wind tunnel tests (See Figure 1.).

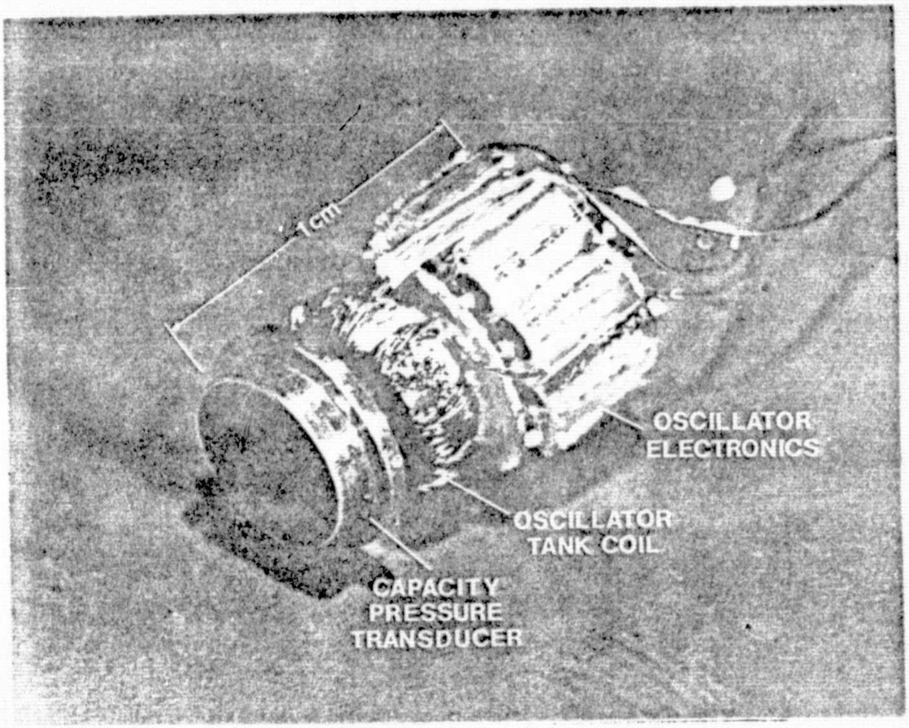


Fig. 1.

NASA-Ames pressure cell originally developed for wind tunnel aeronautical testing.

Although the Ames transducer diaphragm is made of 48% nickle-iron steel, a material highly susceptible to corrosion by body fluids, it can be rendered non-reactive by coating it with parylene (Union Carbide Co.). Two transducers so coated, each having its requisite electronics (LC oscillator) but lacking the telemetry component, were furnished to the Stanford Medical School team for implantation trials. For these preliminary trials, a coaxial cable was used to deliver activating power to bring out the pressure signal (about 9 MHz).

PROCEDURE

The transducer is mounted through a small burr hole drilled through the skull. With its sensitive diaphragm lightly touching the outer lining (dura) of the brain; the scalp is then closed over the unit, and ICP readings taken by the transducer are telemetered to a receiving antenna located near the head. In this way, wires penetrating an open scalp incision, with the probable chance of infection, are eliminated (see Figure 2.).

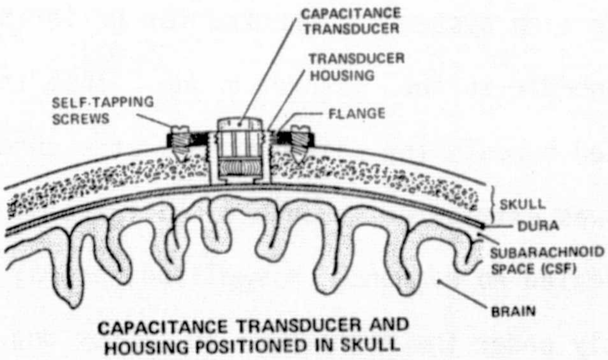


Fig. 2

PROGRESS

Work completed this year was in five major areas:

1. Performing long-term *in vitro* temperature and pressure cycling tests to determine baseline drift.
2. Doing chronic animal implant actions to perfect the surgical technique and detect tissue reaction to the materials used.
3. Presenting papers at scientific meetings to inform colleagues of progress in engineering and surgical aspects of these studies (Refs 7, 8).
4. Interacting with a commercial manufacturer regarding specification and improvements in the original design. Four meetings between the Stanford Team and the commercial manufacturer took place.
5. Obtaining support for data processing equipment necessary to the performance of initial studies in human subjects.

Drift rate and compatibility *in vivo* were observed by implanting two cable-connected transducers in dogs. The cables were placed entirely under the scalp, after each system was checked for calibration against a manometer connected to a needle in the *cisterna magna*. Then the end of the cable was sealed and tucked beneath the skin. When system checks were later desired, this connector was extricated through a small incision in the scalp. Tissue examination revealed no evidence of swelling, edema, or vascularization in the dura directly under the transducer in either dog. This suggests that a titanium transducer with completely sealed telemetry electronics should be suitable for future long-term implantations. In addition, two Ames transducers

having the completed telemetry electronics package, undergoing <u>in-vitro</u> (37^{o} C. water bath) testing showed considerable drift (2 to 3 Torr/day) initially, and so were not considered for implant tests. Their drift rate, however, shows signs of slowing down, and these two may yet be usable for experimental purposes.

Six improved models of the transducers with on-board telemetry packages were ordered by the Ames Research Center, at the beginning of this year. Delivery of these units from the Konigsberg Instrument Company, Pasadena, California, is set for November, 1976. In this model, the transducer, including the 0.003-inch-thick diaphragm, is machined from titanium. The electronics package has been improved and further miniaturized. Also, a single antenna, rather than the original pair of antennas, is used. Non-welded seams are sealed with an epoxy compatible with body fluids.

PLANS

A new Ph.D bioengineer will join our BATeam on a part-time basis to assist with setting up and operating the electronic data recording equipment to be ordered for clinical studies. He will be responsible for transducer calibration and bench testing. Emphasis will be placed on evaluating Konisberg transducer-telemetry units which are to be delivered this fall. The six improved units will begin a series of rigorous laboratory tests (in-vitro, acute implantation, and chronic implantation in animals). If this improved system proves to be stable, clinical tests will begin during 1977.

A calculator-based set of monitoring equipment designed to record, correlate, and present the ICP and associated parameters (e.g., heart rate, end-expired carbon dioxide, mean arterial pressure) will be ordered. Together

with equipment already on loan from the School of Medicine and the Ames-Research Center, a sophisticated data handling system will be assembled. This equipment allows gathering high quality of data needed to gain acceptance for this introcranial pressure monitoring system by the medical profession.

PERSONNEL:

Principle Investigators:	Gerald Silverberg, M.D., Assistant Professor Neurosurgery at Stanford Medical School
	Allen Ream, M.D., Assistant Professor of Anesthesiology, Stanford Medical School
BATeam Coordinator:	Robert J. Debs
NASA Engineer:	Thomas Fryer, Assistant Chief of Electronics Instrument Development Branch

COMMERCIALIZATION ACTIVITIES

COMMERCIALIZATION ACTIVITIES SUMMARY

INTRODUCTION

The overall goal of the NASA Technology Utilization Program is to insure the widest possible dissemination and utilization of technology developed through the aerospace program. An important way in which technology can reach a large number of users is through the manufacturing, marketing and distributing capabilities of private industry. If there appears to be a widespread need within the medical profession for a device based on NASA technology, the Biomedical Applications Teams contact medical instrument manufacturers to determine the feasibility of commercialization. The medical device manufacturing industry is extremely competitive and for each idea which leads to a successful product line, there are hundreds which prove to be commercially unfeasible. One can therefore expect that only a small percentage of proposed technological solutions can ever achieve successful large scale commercialization. However, if the biomedical problems are originated by reliable medical investigators, and the problems are screened for their potential to satisfy a significant need in the medical profession, the liklihood of realizing a commercializable NASA technological solution is increased.

This year the Stanford Biomedical Applications Team has established numerous relationships with medical device manufacturers. The most successful commercialization activities are listed below followed by a brief summary of the present commercialization status. Greater detail on each of these projects is provided in the remainder of this section.

1. <u>Flexible Medical Electrodes</u> - These have been commercially available since January, 1975 through the <u>In Vivo</u> Mertric Systems, Redwood Valley, California, and the manufaturer has already made improvements that were

suggested by the Stanford Biomedical Applications Team. In May, 1976 the manufacturer issued a new product bulletin describing these flexible surface electrodes as a development of NASA technology.

2. NASA Echocardioscope - A commercial product development program is under way involving the Rohe Scientific Corporation. NASA funding to share research and development costs for this commercialization project has been granted. The first of a family of Echocardioscopes based on ultrasound work at the NASA-Ames Research Center are to be delivered in January, 1977.

3. Miniature Biolemetry System - A miniature Biolemetry System designed at the Ames-Research Center for use in the evaluation of children with cerebral palsy has been fabricated and delivered to the Children's Hospital at Stanford. The manufacturer is awaiting clinical validation of this unique system before proceeding with further production.

4. Neurosurgical Pressure - Telemetry System - Konigsberg Instrument Corporation is completing work on a capacitive intracranial pressure transducer complete with telemetry electronics. Delivery of the first units is expected in November, 1976. The company has designed this monitoring system to facilitate mass production. A program of laboratory validation at Stanford University Medical School will begin this fall.

5. On-Line Ventricular Contour Detector - Four medical device manufacturers have requested information on this device as a result of the NASA Biomedical Applications Conference held at the University of Conn. Health Center, September 21, 1976. Detailed technical reports have been supplied to them and we anticipate further collaboration.

FLEXIBLE MEDICAL ELECTRODES

PROBLEM DEFINITION

A medical electrode is a device for monitoring physiological signals. It is usually made of a highly conductive metallic compound which permits the passage of electrical signals from the patient to a recording instrument with minimal signal loss. The largest single use of medicle electrodes is in cardiology for monitoring the electrocardiogram. Applications of medical electrodes include recording brain waves, respiratory activity, and monitoring muscle contraction as previously described in this report (EMG Telemetry in Cerebral Palsy).

While electrodes at first appear to be rather simple devices, lack of understanding of the electrochemical process which takes place at the junction between the skin surface and the metallic surface of the electrode, has lead to difficult problems, particularly in long-term monitoring. Millions of dollars have been spent by industry in developing sophisticated amplification and filtering devices to process the signal derived from the electrode. However, inadequate attention has been focused on the electrode itself, the primary link in the chain of monitoring equipment.

BACKGROUND

NASA has had extensive experience in the development and use of electrodes to monitor physiological signals from astronauts both during space flight and during long-term bed rest studies in space simulation exercises. In 1973, NASA sponsored an international conference entitled "Biomedical Electrode Technology - Theory and Practice". This conference was held at Stanford University and conducted by the Stanford Biomedical Applications Team.

Through efforts of the BATeam, the proceedings of this conference was published in a reference text, Biomedical Electrode Technology - Theory and Practice, edited by Donald C. Harrison, M.D. and Harry Miller. This text is now in its third publication and over a thousand copies have been sold.

COMMERCIALIZATION

Through these efforts by the Stanford Biomedical Applications Team to disseminate NASA technology, biomedical electrodes based on a NASA design have been commercialized. Recently the In Vivo Metric Systems Company, Redwood Valley, California, has made improvements to its new line of flexible skin electrodes (see excerpt of their product bulletin below). These electrodes are based on work with flexible conductive materials at the NASA-Ames Research Center.

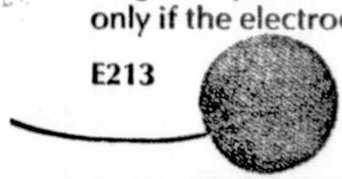
Flexible Skin Electrodes

IVM flexible skin electrodes were developed by NASA technology. Because they are soft and easily conform to the body surface, these electrodes allow long-term monitoring without patient discomfort.

The sensor of each electrode is constructed of elasticized nylon mesh impregnated with silver and chlorided for better signal quality. Resistivity is stable at 1 ohm per square. The cable is securely attached to the electrode with silver-loaded epoxy.

Flexible electrodes may be used dry; however, E404 electrode gel or E407 gel-impregnated pads will improve signal quality. Electrodes are easily attached to the patient with surgical tape, bandages, or adhesive discs (E402). Note: Adhesive discs should be used only if the electrode is used once. All electrodes are supplied without termination pin.

E213

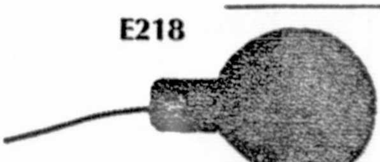


Diameter: 20 mm
Padding: 1.5 mm-thick closed-cell polyethylene foam.
Cable: 1 meter, vinyl insulated wire

E217

Diameter: 20 mm
Padding: 6 mm-thick open-cell foam rubber
Cable: 1 meter, silicon rubber insulated wire
Note: The wire and rim of the electrode are sealed to the padding with silicone rubber. Use of silicone rubber makes the electrode washable and reusable.

E218



Diameter: 20 mm
Padding: None provided.
Cable: 1 meter, vinyl insulated wire
Note: E218 electrodes are available at low cost and well suited for one-time use.

Hayes Products Inc., Seattle, Washington, has also worked with the Stanford BATeam on an improved design of this type of electrode. During this reporting period we offered some suggestions for design improvements.

Also during this year we have provided relevant NASA technical literature on electrodes to Life Technical Instruments, Houston, Texas, and Physio-Control Corporation, Seattle, Washington. We plan to continue to interact with medical device manufacturers and provide them with information on NASA technology in the field of biomedical electrodes.

NASA Echocardioscope

BACKGROUND

An echocardioscope is a device for imaging the heart non-invasively using sound energy. High frequency sound waves are emitted from a transducer and conducted through the chest where they impinge upon the heart (see fig.1 below). Various structures within the heart reflect these pulses of sound energy. The echos are received, processed and displayed to form an image which can be interpreted by the cardiologist.

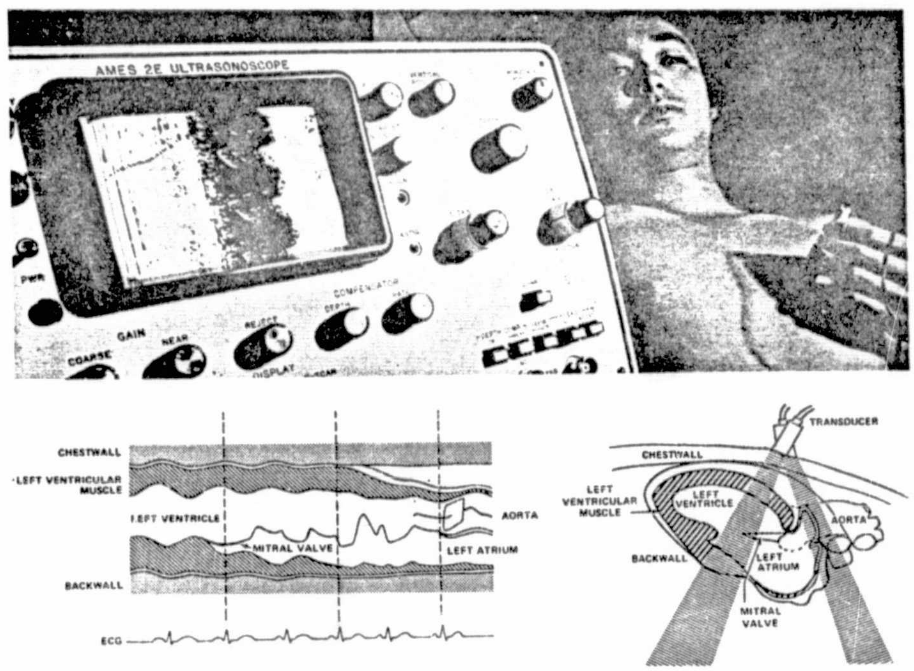


Fig. 1

Top-NASA-developed echocardioscope being used to examine a patient. Below right - ultrasonic beam is directed at different heart structures. Below left - changes in echo patters as different structures are visualized.

NASA TECHNOLOGY

NASA engineers have been developing echocardioscopes for several years. The most recent NASA contributions to this field have been published in the reference text, Cardiovascular Imaging and Image Processing - Theory and Practice, 1975 edited by Donalc C. Harrison, Harold Sandler, and Harry Miller. The specific echocardioscope depicted (Fig. 1) is one of a series of prototypes being developed for use in conjunction with the Space Shuttle program.

COMMERCIALIZATION PROGRESS

During this reporting period, the Stanford Biomedical Applications Team met with leading manufacturers of ultrasound equipment in the United States. Representatives of the Rohe Scientific Instrument Company, Pasadena, California, agreed to begin preliminary engineering redesign of the portable batter-powered echocardioscope originally intended for use in space. Their goal is to develop a moderately priced single transducer instrument for use in hospitals and clinics. Their engineering staff is making modifications to update the electronics in this device, incorporate integrated circuitry and make it modular for easy serviceability. Commercialization plans call for developing a family of echocardioscopes. The first production prototypes are to be completed by January, 1977; to be followed shortly thereafter by a more advanced array device, capable of two dimensional imaging based on the NASA-Ames 3E Ultrasonoscope shown in figure 2. Rohe has applied for a non-exclusive license to manufacture this instrument.

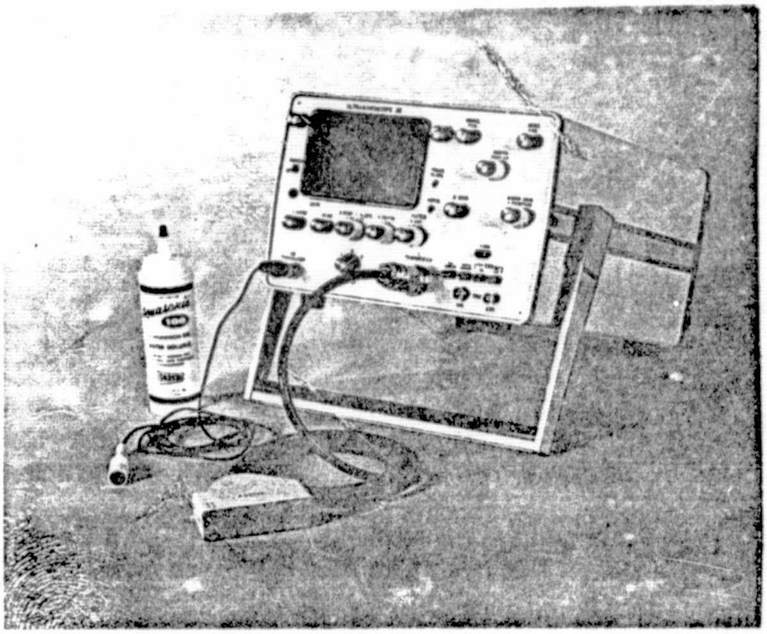


Fig. 2

NASA-Ames Research Center 3E Ultrasonoscope with both single transducer and linear array transducer.

Funding to allow cost sharing of the additional design work needed to make the NASA instrument commercially feasible has been granted. A contract between the Stanford Biomedical Application Team and the Rohe Company has been formulated. Signing of this contract has been delayed pending approval of a merger of Rohe Scientific with North American Phillips Corporation. We anticipate that our commercialization plan with Rohe will proceed on schedule once the proposed merger is approved by the Federal Trade Commission

MINIATURE BIOTELEMETRY SYSTEM

NASA technology, and implementation of this project has been previously described under the heading (EMG Telemetry and Cerebral Palsy). The biotelemetry system developed for this project required the close interaction between members of the BATeam, NASA-Ames Research Center, and the L&M Electronics Corporation. During this reporting period numerous meetings were held with the manufacturer to determine specifications, make electronic component selections, and determine packaging requirements. Human factor engineering considerations included the following:

1. The transmission equipment had to be easily applied to and removed from the child.
2. Use of the equipment in the clinical laboratory was to require a minimal understanding of RF telemetry.
3. The transmitter had to be rugged to withstand falls and rough handling by children.
4. The transmitter should be disguised to increased their acceptance by very young pediatric patients.

PLANS

Further production of this biotelemetry system has been discussed with the manufacturer. Future orders for this device will be accepted only after thorough clinical trials have been completed, thus allowing ideas for improvements based on these trials. Possible improvements could include reducing the transmitter electronics to a single intergrated circuit chip (thus reducing the size of the transmitter by half) and utilizing a simpler FM-FM telemetry approach. Once clinical trials with the pre-production prototype are satis-

factorily completed at Stanford Children's Hospital this system will be offered to the other gait laboratories in the United States which are listed in the registry compiled by the Committee on Prosthetics Research and Development of the National Academy of Sciences. Use of this miniature bio-telemetry system is not limited to monitoring the EMG. It can also be used for telemetering other physiological signals such as the electrocardiogram, body temperature, blood pressure, etc.

INTRACRANIAL PRESSURE MONITORING SYSTEM

The Konigsberg Instrument Inc, Pasadena, California, is now fabricating pre-production prototype intracranial pressure transducers with accessory telemetry electronics. The transducer design has gone through four inter-actions with emphasis placed on achieving a production line model. The associated electronics for telemetering the intracranial pressure signal has been made compatible with secondary transmission via a crystal-controlled FM transmission at 88 MHz. As in the previous commercialization project, production of additional units must await rigorous laboratory and animal validation studies. Satisfaction completion of these preliminary tests will be followed by clinical trials in neurosurgical patients at Stanford University and Santa Clara Valley Medical Centers. Although this is an implantable device, it can be used in research applications without pre-market clearance under provisions of the new medical device legislation. The manufacturer is aware of medical device clearance procedures and is planning to file for approval by the appropriate FDA standards planel.

ON-LINE VENTRICULAR CONTOUR DETECTOR

PROBLEM DEFINITION

During the analysis of X-ray motion pictures of the heart, the calculation of various anatomic quantities is based on measurements which are presently made by hand. Because calculations based on these measurements lead cardiologists to a specific diagnosis and recommendation for either medical treatment or surgery, the accuracy and repeatability of these manual measurements is important. To reduce the human error and time involved in this process, on-line computerized methods are being developed by NASA for rapidly detecting and analyzing X-ray images of the heart (Ref. 9).

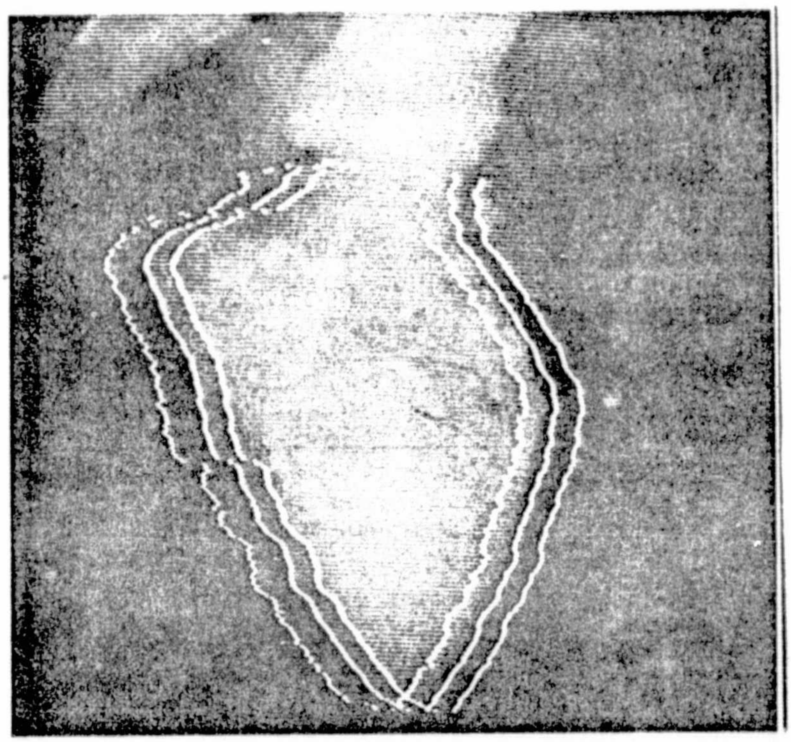
RELEVANT NASA EXPERTISE

Analog and digital computer-graphic methods have been developed at the NASA-Ames Research Center for analysis of X-ray images of the heart. These techniques have been developed to analyse X-rays of laboratory animals taken during stress testing before, during and after simulated space flights.

APPROACH

A significant portion of the anatomy of the heart that is revealed during X-ray studies is the outline or contour of the left ventricle, the main pumping chamber of the heart. The size, shape, and movement of the walls of the heart are directly related to the ability of the heart to function as an efficient pump. To make the outline or contour of the heart visible to X-rays a special dye is first injected into the ventricle. As this dye is pumped out of the heart, X-ray motion pictures are taken. These are recorded both by video and cine techniques. An image of the ventricle can be displayed on a video monitor

as shown in the figure below. With the use of a computer this image is scanned and multiple white line contours or outlines are rapidly and automatically drawn (see figure).



Computer Drawn Ventricular Outlines of X-ray Image of Human Heart.

The coordinates of this outline are stored in the computer's memory. These coordinates are used to make a printed tracing of the image and to perform a large number of calculations which tell the heart specialist such important information as the size of the heart, the amount of blood ejected with each beat, and the amount of contraction taking place in different portions of the heart. This working system has been shown to be accurate within two percent when predicting the volume of plastic casts of hearts for which the exact

volume is known.

STATUS

A team from Stanford consisting of cardiologists, a computer programmer, a computer hardware engineer, a biomedical engineer have reviewed and evaluated this automated ventricular contour detection system. At present, it is not ready for direct transfer to the hospital for use in patients. Proposals to continue to refine this system utilizing the image processing expertise of scientists at the Jet Propulsion Laboratory, Pasadena, California, are in preparation.

This system was described to a group of New England Company representatives at the University of Connecticut Health Center in September, 1976. Four corporations requesting additional information were:

Instrumentation Laboratory Inc., Lexington, Massachusetts
PARA Company, West Hartford, Connecticut
New England Nuclear, North Billerica, Massachusetts
Electronic Associates Inc., Wilone Branch, New Jersey.

Reprints from the Cardiovascular Imaging and Image Processing Conference and NASA Technical Reports describing this sytem were subsequently sent to these companies.

ADDITIONAL ACTIVITIES

PUBLIC INFORMATION ACTIVITIES

One of the functions of the Biomedical Applications Teams is to inform the scientific community and general public of NASA technological developments and capabilities which are being applied to solving medical problems. In order to disseminate scientific information and increase public awareness of NASA biomedical activities, the Stanford team has completed two major projects during this past year. The first was the publication of the proceedings of the Third International Symposium On Biotelemetry, and the second has been the completion of the motion picture, "Dividends From Space", which illustrates the functions of the Biomedical Applications Team program.

BIOTELEMETRY III

The proceedings of the NASA-sponsored Third International Symposium on Biotelemetry have been edited into a reference text entitled Biotelemetry III, and representing the work of 82 contributors. The editors are Thomas Fryer and Harold Sandler, M.D. both from the NASA-Ames Research Center and Harry Miller, Paul Purser, and Manley Hood, members of the Stanford Biomedical Applications Team. Copies of this 400 page text may be purchased through the Ordering Department, Academic Press, Inc., 11 5th Ave, New York, 1003. It will sell for approximately $25,00 in hardback form, available in December, 1976.

DIVIDENDS FROM SPACE

During this reporting period, the twenty-two minute, color motion picture, "Dividends From Space - Biomedical Applications of Aerospace Technology" has been completed and the first four prints delivered. This film uses examples of successful transfers of NASA Technology in such diverse areas of medicine as Pediatrics, Cardiology and Neurosurgery. The film was produced in cooperation with Film Media, Incorporated, Santa Clara, California. This film is intended

for use at engineering and medical meetings, community meetings, by television networks, and in academic training programs. An abstract of the film follows:

> The spectacular accomplishments of the Manned Space Program have made NASA a household word. Less appreciated is the fact that NASA has established a Technology Utilization Program to insure that advances in aerospace technology are reapplied to the solution of industrial, social, and medical problems. This 20 minute color film illustrates the philosophy and function of the Biomedical Applications Team within NASA'S Technology Utilization Program. Each of the four regional Biomedical Applications Teams has a particular area of emphasis. The Stanford Team operates within the Cardiology Division of the Stanford University School of Medicine and is monitored by the NASA-Ames Research Center. Emphasis is placed on adaptation of aerospace instrumentation to the diagnosis and treatment of heart disease. Projects illustrating its scope of activities are: 1) an on-line, computerized, ventricular outline analyzer, 2) an implantable, miniaturized, intracranial pressure telemetry system, 3) a portable, battery-powered, ultrasonic echocardioscope, 4) an ultra-flexible biomedical electrode, 5) an electromyographic telemetry system for the gait analysis of crippled children. These approaches to solving medical problems require the close cooperation of engineers, physicians, nurses, physical therapists, and electronics technicians who pool their talents in an effort to utilize advanced technology to improve the quality of patient care.

This film has been accepted for showing at the San Diego Biomedical Symposium in February, 1977 and also the Twelfth Annual Meeting of the Association for the Advancement of Medical Instrumentation (AAMI) in March, 1977. The Stanford BATeam will work with the NASA Office of Public Affairs to obtain additional copies of the film and schedule nation wide showings.

NEW MEDICAL PROBLEM AREAS

NEW BIOMEDICAL PROBLEM AREAS

CEREBRAL PALSY COMMUNICATION DEVICE

To provide a synthetic speech device for use by non-vocal cerebral palsied children.

BACKGROUND

There is a large number of people who cannot speak and who have inadequate use of their hands and arms eliminating other forms of non-verbal communication such as writing and sign language. This group of patients includes those with spinal cord injuries, head injuries, stroke and patients with cerebral palsy. Patients with cerebral palsy frequently have normal intelligence but lack proper coordination of the muscles involved in speaking, writing and walking. The degree of motor impairment in cerebral palsy varies greatly from patient to patient. A communication system for such patients would therefore need to have an adaptable interface which is tailored to the capabilities of each patient.

NASA TECHNOLOGY

Within the Man Machine Integration Branch at the NASA-Ames Research Center, a team of engineers (computer programmers, and a voice research specialist) are working on the problem of man-machine voice communications. They are developing programs and hardware for both speech recognition and speech synthesis.

Their work is in flight management systems in which speech input is used by pilots to issue aircraft control commands, thus reducing the number of switches and controls which must presently be activated manually. They are evaluating speech input as a way of reducing the complexity of the pilot's task and increasing

his efficiency, particularly in advanced aircraft such as the vertical take-off and lander (VTOL). They are also developing a speech synthesizing system which would give the pilot verbal information regarding such flight parameters as altitude and engine thrust during critical phases of landing, while the pilot's eyes must be fixed on the runway. NASA-Ames investigators are enthusiastic about the possibility of using the speech recognition and synthesis systems as communications aids for the speech-impaired patient.

PROBLEM STATUS:

This problem is still in the exploratory and discussion phase. In addition to meetings at the Stanford Children's Hospital and the NASA-Ames Research Center, we have discussed this problem with biomedical engineers at the Research Triangle Institute BATeam. RTI has begun simular discussions with rehabilitation centers on the east coast, including the United Cerebral Palsy Association of Nassau County, The Bernard Fineson Developmental Center, and the Gifted Handicapped Center at the University of North Carolina. We intend to coordinate our activities with the RTI BATeam in identifying NASA technology applicable to this problem.

LIQUID COOLED GARMENT APPLICATIONS

OBJECTIVES

To evaluate a NASA-developed liquid cooled garment in both research and patient care applications at the Stanford University Medical Center.

BACKGROUND

There is a need for better methods of lowering the body temperature of patients being treated for a variety of medical problems.

1. Hypothermia is gaining increasing acceptance in the specialty of cardiovascular surgery. Because lowering the body temperature decreases matabolic rate and oxygen consumption, hypothermia has become an accepted alternative to cardiopulmonary bypass in the performance of open heart surgery on infants.

2. Surface cooling is being used prior to cardiopulmonary bypass (using the heart-lung machine) to allow reaching low body temperatures more rapidly.

3. Lowering body temperature has been shown to have a protective effect on patients with elevated intracranial pressure and further research is being done in this area.

4. Better methods of controlling fever are needed in patients with infection or who have brain injury. Presently available cooling blankets are inadequate for these problems. They do not provide close enough contact with a large enough body surface area to achieve the desired level of cooling. In addition it is difficult to regulate the temperature of these cooling blankets with the desired degree of control.

NASA TECHNOLOGY

Liquid cooling garments (LCG) have been developed within the space program to protect astronauts from adverse thermal conditions during extra vehicular activity. Investigators at the NASA-Ames Research Center have made improvements on the original LCG's used during the Appollo missions. These new garments utilize

a flexible polymer that has thousands of tiny channels inscribed in it through which cold water is circulated. Close contact with the body surface is maintained by incorporating cooling panels made from this material inside an elastic suit made of spandex.

PROJECT STATUS

Ames Research Center physiologist and engineers have met with doctors at the Stanford University Medical School in the Departments of Neurosurgery and Anesthesiology to specify requirements for a liquid cooled garment to be used in the four areas listed above. They have agreed upon a design which allows continuous cooling of the patient without interferring with the routine nursing care. The loan of a liquid cooled garment and its attendant refrigeration unit is anticipated during December, 1976.

PERSONNEL

Gerald Silverberg, M.D.
Stanford University
Medical School

Allen Ream, M.D.
Stanford University
Medical School

Gene Schmidt, M.D.
BATeam Coordinator

Bill Williams
NASA-Ames Research Center

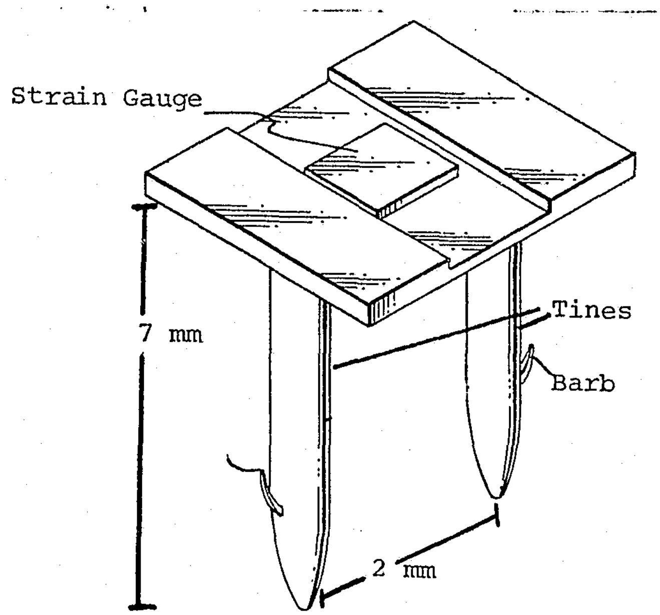
Bruce Webbon
NASA-Ames Research
Center

MINIATURE CARDIAC FORCE TRANSDUCER

Objective: To utilize NASA developed miniature cardiac force transducers to investigate the effects of myocardial ischemia in laboratory animals.

Background: One very important research area in Cardiology is determining the effects of coronary artery occlusion on the contractility of heart muscle. Knowing how heart muscle is affected by the sudden loss of blood flow through the coronary arteries has direct bearing on the outcome of heart attack victims.

NASA Technology: Several designs for miniature transducers which would be applicable to cardiac research have been developed at the Jet Propulsion Laboratory (JPL) under NASA sponsorship. JPL scientists R.H. Silver, G. W. Lewis, C. Feldstein, E. N. Durand, and J. C. Fletcher have been issued a patent on the transducer depicted in the drawing below.



The miniature transducers would be one cm across and have tines from seven to eleven mm in length. As shown in the figure the tines would have barbs to secure them into the heart muscle and wires running from the transducing element would provide a measurement of contractile force.

Proposed Application: The Stanford University Division of Cardiology has an NIH funded Program Project Grant entitled "Pharmacologic and Physiologic Basis of Cardiac Therapy". As part of this program in investigating new modalities for treatment of heart disease, Stanford researchers are studying the effects of artificially produced ischemia in laboratory animals. Specifically, the work calls for the recording of both myocardial contractile force and regional "cardial electrogram" in open chested dogs during acute coronary artery ligation. An array of six contractile transducers serving the double purpose of providing a localized ECG signal would be used to map the "zone of ischemia" produced by sudden interruption of the blood flow through the coronary arteries.

Problem Status: The Jet Propulsion Laboratory has submitted a proposal to NASA to make improvements upon an earlier design for the miniature force transducer. Approval of this proposal would allow the Stanford Biomedical Applications Team to work with Jet Propulsion Laboratory scientists in applying these miniature transducers to this very important area of Cardiology pharmacological research.

Transducers furnished by JPL would be used to study the effect of accepted and investigational pharmacological agents used in the treatment of heart patients. How these cardiac drugs affect contractile force and the size of the heart muscles are important medical questions to be answered if one is to develop a rational basis for treating heart attack patients.

Time Schedule: Implementing these force transducers in the animal research laboratories at Stanford is dependent upon funding of the JPL proposal to develop these transducers. The need at Stanford is for six of these units with their appropriate signal conditioning electonics for implantation in open chested dogs. The planned experiments with the transducers will be scheduled so that all studies can be completed within three months of receipt of the required units from JPL.

APPENDIX A - PUBLICATIONS RESULTING FROM B.A.TEAM PROJECTS

1. Bleck, E. E., Ford, F.: Electromyographic Telemetry Analysis of Gait Patterns in Normal and Spastic Cerebral Palsied Children with Special Reference to the Quadriceps and Hamstring Muscles. Read at the November, 1974 meeting of the American Academy for Cerebral Palsy in Denver, Colorado. Submitted for publication to Journal of Developmental Medicine and Child Neurology.

2. Ford, F., Bleck, E. E., Collins, F. J.: The Effects of Dantrolene Sodium on the Gait and Motor Function of Children with Spastic Cerebral Paralysis - Objective Measurements Compared with Subjective Responses; submitted to Journal of Developmental Medicine and Child Neurology.

3. Ford, F., Rositano, S., Schmidt, E. V.: Clinical Pediatric Gait Biotelemetry, Biotelemetry III, Proceedings of the Third International Symposium on Biotelemetry, May 17 - 20, 1976, Academic Press, New York. (In Press).

4. Westbrook, R. M., Fryer, T. B., Rositano, S. A.: A Wideband EMG Telemetry System. Ibid.

5. Schmidt, E. V., Debusk, R. F., Popp, R. L.: Proposed Applications of lower body negative pressure to cardiology. Proceedings of the Eighth Conference on Space Simulation, November 3 - 5, 1975, NASA SP-379.

6. Schmidt, E. V., Debusk, R. F., Popp, R. L.: Applications of lower body negative pressure testing to cardiology. AAMI Journal, (abstract) Cardiovascular Hemodynamics Section, March 22, 1976.

7. Fryer, T. B.: A Pressure Telemetry System Utilizing a Capacity Type Transducer. Proceedings of the Third International Symposium on Biotelemetry, May 17 - 20, 1976, Academic Press, New York. (In Press).

8. Silverberg, G. D., Ream, A. K., et al: Intracranial Pressure Monitoring using Implanted Epidermal Capacitance Transducer and Telemetry. Ibid.

9. Reiber, J. A.: Real Time Detection and Data Acquisition for the Left Ventricular Outline, NASA Technical Report, NASA TR R-461, June, 1976.

APPENDIX B - MEDICAL DEVICE MANUFACTURES

Below is a list of Medical Device Companies that are working with the Stanford BATeam on the Commercialization of technology derived from aerospace research and development.

In Vivo Metric Systems
P. O. Box 217
Redwood Valley, California 95470

Konigsberg Instruments, Inc.
2000 East Foothill Blvd.
Pasadena, California 91107

L & M Electronics Company
2401 Geneva Avenue
Daly City, California 94014

Rohe Scientific Corporation
2158 South Hathaway Street
P. O. Box 10760
Santa Ana, California 92711